PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATERIAB

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

International application No. International diagnostic (day/monity/ear) 15.07.2003 15.07	A == 11 ==	ante es agents file refe	rence					
International application No. POETTABEZIOAA00308B International Patent Classification (IPC) or national classification and IPC GOTN33543, GOTN2155 Applicant DENSHAM, Daniel Henry 1. This report is the international preliminary examination report, established by this international Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. sent to the applicant and to the International Bursay) a total of sheets, as follows: a. sent to the applicant and to the International Bursay) a total of sheets, as follows: a. sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.18 and Section 607 of the Administrative Instructions). sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 4. This report contains indications relating to the following items: Box No. II Priority	Applicant's or agent's file reference JWJ01059WO			FOR FURTHER ACTION See Form PCT/PEA/416				
International Patent Classification (IPC) or national classification and IPC GOTN33543, GOTN21/55 Applicant DENSHAM, Daniel Henry 1. This report is the international preliminary examination report, established by this international Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. sent to the applicant and to the International Bureau) a total of sheets, as follows: a. sent to the applicant and to the International Bureau) a total of sheets, as follows: and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative instructions). sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the International application as filed, as indicated in term 4 of Box No. I and the Supplemental Box. b. (sent to the International Bureau only) a total of (indicate type and number of electronic parameters), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 4. This report contains Indications relating to the following items: Box No. II Basis of the opinion Box No. IV Leck of unity of Invention Box No. IV Leck of unity of Invention Box No. VI Certain documents cited Box No. VI Certain defects in the International application Box No. VI Certain defects in the International application Box No. VI Certain defects in the International application Box No. VII Certain defects in the International application Date of submission of the demand Date of completion of this report 15.09.2005 Name and mailing address of the International preliminary examining sufficinty; Press of the International	Interne	ational application No.			month/year)	The state of the s		
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/003088

	Box	No. I Basis of the report			
1.	With	Vith regard to the language , this report is based on the international application in the language in which it was iled, unless otherwise indicated under this item.			
		This report is based on transl which is the language of a tre	ations from the original language into the following language , Inslation furnished for the purposes of:		
		☐ international search (under publication of the international preliminary experiments)	or Rules 12.3 and 23.1(b)) ional application (under Rule 12.4) examination (under Rules 55.2 and/or 55.3)		
2.	With regard to the elements* of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):				
	Des	scription, Pages			
	1-5		as originally filed		
	Cla	alms, Numbers			
	1-1-	4	received on 18.05.2005 with letter of 16.05.2005		
	Dra	awings, Sheets			
	1/1		as originally filed		
		a sequence listing and/or ar	y related table(s) - see Supplemental Box Relating to Sequence Listing		
3	. 🗆	The amendments have resu	ulted in the cancellation of:		
		☐ the description, pages☐ the claims, Nos.			
		☐ the drawings, sheets/figs	S		
		☐ the sequence listing (sp.☐ any table(s) related to se	ecify): equence listing <i>(specify)</i> :		
4	4. □ ha Sı	This report has been estable ad not been made, since they upplemental Box (Rule 70.2(c)	lished as if (some of) the amendments annexed to this report and listed below have been considered to go beyond the disclosure as filed, as indicated in the)).		
		☐ the description, pages☐ the claims, Nos.			
		☐ the drawings, sheets/fig	s "		
		☐ the sequence listing (sp☐ any table(s) related to s	equence listing (specify):		
	*	. Tf item 4 applies. E	ome or all of these sheets may be marked "superseded."		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/003088

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
		nvent ble h	ion appears to be novel, to involve an inventive step (to be non- ave not been examined in respect of:			
	the entire international application,					
Ø	claims Nos. 13-14					
	because:					
×	the said international application, or the said claims Nos. 13-14 relate to the following subject matter which does not require an international preliminary examination (specify):					
	see separate sheet					
	that no meaningful opinion could be formed (specify).					
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.					
	no international search report has been established for the said claims Nos.					
	to a standard provided for in Annex					
	the written form		has not been furnished			
			does not comply with the standard			
	the computer readable form		has not been furnished			
			does not comply with the standard			
	the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.					
	See separate sheet for further	deta	uils			

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 2,9,11

No: Claims 1,3-8,10,12-14

Inventive step (IS) Yes: Claims 2

No: Claims 1,3-14

Industrial applicability (IA) Yes: Claims 1-12

No: Claims 13-14

2. Citations and explanations (Rule 70.7):

see separate sheet

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item III

The scope of present claims 13-14 does not explicitly exclude embodiments relating to subject-matter related to diagnostic/detection methods that are carried out "in vivo" involving the treatment, of the living human/animal body by implantation of the sensing elements by surgery. The referred subject-matter is considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT and consequently, no report will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34 (4) (a) (I) PCT).

item V

1.) Reference is made to the following documents:

D1: A. J. Haes & R. P. Van Duyne (2002) J. Am. Chem. Soc. 124, 10596-10604

D2: S.-F. Cheng & L.-K. Chau (2003) Anal. Chem. 75, 16-21

D3: L. Andrew Lyon et al (1999) Sensors & Actuators B 54, 118-124

D4: L. He et al (2000) J. Am. Chem. Soc. 122, 9071-9077

D5: WO-A-01/09388

D6: WO-A-99/05315

D7: WO-A-01/20295

D8: N. Lochner et al (2003) Eur. J. Pharma. Biopharma. 56, 469-477

2.) The subject-matter of claims 1, 3-8, 10 and 12-14 is not novel within the sense of Art. 33

(2) PCT, for the following reasons:

D1 discloses a localized surface plasmon resonance nanobiosensor comprising a monolayer (a matrix) of biotinylated silver nanoparticles covering a glass surface (see figs. 1-5; abstract). D1 anticipates the subject-matter of claims 1, 3, 5, 7-8, 10 and 12-14.

D2 discloses a fiber-optic evanescent-wave sensor comprising an unclad portion modified with a self-assembled monolayer of colloidal gold particles (p. 16-17). D2 anticipates the subject-matter of claims 1, 3-7, 10 and 12-14.

D3-D5 discloses the use of colloidal gold particles for the enhancement of SPR-based

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

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sandwich assays. In this assay, the binding event is detected by a large shift in plasmon angle caused by aggreggation of nanoparticle-labels on the sensor surface (D3, p. 118-119; D4, p. 9072-9073 and D5, examples 1-3). D3-D5 anticipate the subject-matter of claims 1, 3-8, 10 and 12-14.

- 3.) The subject-matter of dependent claims 9 and 11 (partially, as referring to claim 1) is considered to be novel (Art. 33 (2) PCT), but not inventive within the sense of Art. 33 (3) PCT because it relates to obvious alternatives of the sensor element of claim 1, which fall within the routine practice in this technical field and which do not seem to result in any unexpected technical effect.
- 4.) The subject-matter of claims 2 (complete) and 9, 11 (partially, as dependent thereon) is considered to be novel and inventive within the sense of Art. 33 (2) and (3) PCT, for the following reasons:

The sensing element of claim 2 differs from that of D1 (closest state of the art) in that it comprises multiple particles that are stacked within a matrix.

The devices of D1-D3 comprise matrices which are formed by deposition of a monolayer or a sub-monolayer of metallic particles on a solid support (see D1, fig. 1; D2, p. 17, l. col.; D3, p. 118, r. col.). Analogous arguments apply for the devices of D4-D5, in which the particles are used for labeling a binding partner (see D4, p. 9073, l. col. and D5, p. 4, l. 5-7). The devices of D6-D7 (see figures) do not comprise any particulate sensing element.

The skilled person equipped with the teaching of D1-D7 would not be motivated to modify the sensing element of D1 by having a matrix comprising multiple particles stacked therein, as claimed in claims 2 (and 9, 11 as dependent thereon) for improving the sensitivity of the sensor. A matrix comprising multiple discrete particles stacked therein, wherein the particles are capable of supporting surface electromagnetic waves generates an evanescent field that extends much deeper into the solution, thereby "sensing" a larger amount of sample, which results in an increase of the sensor signal.

5.) D8 discloses the use of microplate substrates coated with silver nanoparticles for the enhancement of the signal in fluorescence-based immunoassays (see fig. 1). This document

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

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may be relevant when the application enters the regional phase in the case of an invalid priority date.